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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,015	02/17/2006	Dan P. Felsenfeld	02420/100M761-US1	9430
7278	7590	06/23/2009	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			WANG, CHANG YU	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,015	Applicant(s) FELSENFELD ET AL.	
	Examiner Chang-Yu Wang	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 8-17 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-7 and 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/16/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed 3/17/09 is acknowledged. Claim 5 is cancelled. Claims 6 and 7 are amended. Claims 18-25 are newly added. Claims 1-4, 6-17 and newly added claims 18-25 are pending in this application. Claims 1-4 and 8-17 are withdrawn with traverse (filed on June 2, 2008) from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. In addition, new claim 25 is directed to a method, which is withdrawn from consideration. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/2/08.
2. On p. 11 of the response, Applicant argues that independent claim 1 is not anticipated by the cited US Patent No. 6576607 because the peptide of claim 6 used in the claimed method has been amended to recite "an isolated peptide derived from the ankyrin binding domain of an L1-CAM family member protein comprising an amino acid sequence SEQ ID NO:2 wherein the peptide promotes neurite outgrowth". Applicant's arguments have been fully considered but they are not persuasive.

In response, based on MPEP § 1875, § 821.01 & 371 rule, the restriction is deemed proper because the peptide of claim 6 comprising an amino acid sequence SEQ ID NO:2 is still read as encompassing the full-length L1 so that independent claim 1 is anticipated by the prior art as set forth in the office action mailed 9/17/08; and thus, the instant application lacks unity of invention. In addition, the restriction has been made

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final. Based on MPEP§ 821.01-821.04, Applicant may take other appropriate action or file a petition under 37 CFR 1.144 for review of the restriction requirement.

3. Claims 6-7 and 18-24 are under examination with respect to SEQ ID NO: 2 in this office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

5. Applicant's arguments filed on 3/17/09 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Drawings

6. The objection to drawings/figures 7A, 7B, 8A and 8B is withdrawn in response to Applicant's argument on p. 12 of the response.

Specification

7. The objection to the specification is withdrawn in response to Applicant's amendment to the title and abstract.

Claim Rejections/Objections Withdrawn

8. The objection to claim 5 is moot because the claim is canceled.

Claim Rejections/Objections Maintained

In view of the amendment filed on 3/17/09, the following rejections are maintained.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising an isolated peptide comprising or consisting of **the** amino acid sequence of SEQ ID NO:2 and a pharmaceutical acceptable carrier or enabling for a pharmaceutical composition comprising a fusion protein consisting of the amino acid sequence of SEQ ID NO:2 fused to the amino acid sequence of SEQ ID NO:6 and a pharmaceutical acceptable carrier for inhibiting binding of an ankyrin protein to L1-CAM and thereby to promote neurite outgrowth in neurons in vitro or in vivo, does not reasonably provide enablement for an isolated peptide consisting of **an** amino acid sequence SEQ ID NO:2 or SEQ ID NO:3 as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 20 and 24 as amended are drawn to an isolated peptide consisting of an amino acid sequence SEQ ID NO:2 or SEQ ID NO:3.

On p. 14 of the response, Applicant argues that instant claims are enabled. Applicant's arguments have been fully considered but they are not persuasive.

First, the recitation of "an isolated peptide consisting of an amino acid sequence SEQ ID NO:2 or SEQ ID NO:3" as in claims 20 and 24 is interpreted as "an isolated peptide consisting of an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3", which encompasses any fragment derived from the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3.

In contrast to Applicant's arguments, neither the specification nor the prior art teaches that any fragment with any size derived from SEQ ID NO:2 is enabled for promoting neurite outgrowth. The specification only teaches an isolated peptide comprising or consisting of the amino acid sequence of SEQ ID NO:2 or a fusion protein consisting of the amino acid sequence of SEQ ID NO:2 fused to the amino acid sequence of SEQ ID NO:6 that is capable of promoting neurite outgrowth. The specification fails to teach that any fragment with any amino acid residues from SEQ ID NO:2 or SEQ ID NO:3 is able to promote neurite outgrowth. The specification fails to teach what specific amino acid sequences, structures, common features are required for an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3 to preserve the activity of SEQ ID NO:2 in promoting neurite outgrowth. Thus, it is unpredictable what an amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3 are and have the activity of promoting neurite outgrowth. Accordingly, a skilled artisan cannot contemplate what other fragments of SEQ ID NO:2 or 3 are and thus would be within the scope of the claims.

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The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, it is unpredictable what changes which can be made and still maintain activity, and thus the experimentation left to those skilled in the art is extensive and undue. See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1986). Thus, the skilled artisan cannot readily make and use the claimed invention as currently claimed without further undue experimentation. Note that

"The 'predictability or lack thereof' in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971)" See MPEP § 2164.03

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by either Tuvia et al. (*Proc. Natl. Acad. Sci. USA*. 1997. 94: 12957-129562, as in IDS) as evidenced by Davis et al. (*J. Cell Biol.* 1996, 135:1355-1367). Claims 6, 18, 19, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Garver et al. (*J. Cell Biol.* 1997. 137: 703-714, as in IDS) as evidenced by Davis et al. (*J. Cell Biol.* 1996, 135:1355-1367). These rejections are maintained for the reasons made of record.

Claims 6, 18, 19, and 21 as amended are drawn to an isolated peptide derived from the ankyrin binding domain of an L1-CAM family member protein comprising or consisting essentially of an amino acid sequence SEQ ID NO:2 and a pharmaceutical composition comprising the claimed peptide and a pharmaceutical acceptable carrier for promoting neurite outgrowth.

On p. 15-16 of the response, Applicant argues that independent claim 6 has been amended to recite that the claimed peptides are derived from the ankyrin binding domain of an L1-CAM family member protein” and thus excludes the full length L1-CAM family member proteins. Applicant further argues that claim 6 has also amended to recite the function of the claimed peptide in promoting neurite outgrowth. Applicant argues that neither Tuvia nor Garver teaches such peptide because the full length L1-CAM family member protein (L1 or neurofascin) contains a FIGQF motif, which would affect its activity in promoting neurite outgrowth. Applicant’s arguments have been fully considered but they are not persuasive.

In contrast, as previously made of record, Tuvia or Garver does teach a peptide comprising the amino acid sequence of SEQ ID NO:2 because in addition to teaching a FIGQY->F mutant of L1 or neurofascin, Tuvia or Garver teaches L1 or neurofascin (see p. 1298, in particular). The amino acid sequence of L1 or neurofascin comprising the amino acid sequence of SEQ ID NO:2 is evidenced by Davis based on the sequence alignment set forth in the previous office action.

In addition, the recitation of “consisting essentially of an amino acid sequence SEQ ID NO:2” as recited in instant claim 19 is interpreted as “comprising an amino acid

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sequence SEQ ID NO:2 since the claim fails to specify what the basic and novel characteristics actually are within the claimed invention. See MPEP § 2111.03 [R-3].

“A consisting essentially of’ claim occupies a middle ground between closed claims that are written in a consisting of’ format and fully open claims that are drafted in a comprising’ format.” PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir.1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. See MPEP § 2111.03 [R-3].

Further, the recitation of “comprising an amino acid sequence SEQ ID NO:2” is interpreted as “comprising an amino acid sequence of SEQ ID NO:2”, which includes comprising fragments of SEQ ID NO:2. Thus, the protein of neurofascin (or L1) or the protein with a FIGQY->F motif as taught by Tuvia or Garver meets the limitations of claims 6, 18, 19, 21 and 22.

It is noted that the preamble of “derived from the ankyrin binding domain of an L1-CAM family member protein recited in independent claim 6 does not change the composition of the claimed peptides that have the limitation of the protein comprising an amino acid sequence SEQ ID NO:2 as recited in instant claims 6 and 19, which is anticipated by the protein of neurofascin (or L1) or the protein with a FIGQY->F motif as taught by Tuvia or Garver. In addition, the protein of neurofascin or L1 is able to promote neurite outgrowth. Note that

“Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. ‘There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.’ In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA1977).” See MPEP § 2112 [R-3]

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In addition,

"The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). " See MPEP § 2112.01 [R-3].

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 7, 18-19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuvia et al. (Proc. Natl. Acad. Sci. USA. 1997. 94: 12957-129562, as in IDS) or Garver et al. (J. Cell Biol. 1997. 137: 703-714, as in IDS) as evidenced by Davis et al. (J. Cell Biol. 1996, 135:1355-1367)in view of US 6025140 (Langel et al. issued Feb 15, 2000).

Claims 6, 7, 18-19, and 21-23 as amended are drawn to an isolated peptide derived from the ankyrin binding domain of an L1-CAM family member protein

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comprising or consisting essentially of an amino acid sequence SEQ ID NO:2 and a pharmaceutical composition comprising the claimed peptide and a pharmaceutical acceptable carrier for promoting neurite outgrowth. Dependent claim 7 and 23 are drawn to a peptide comprising an amino acid sequence SEQ ID NO:2 linked to an isolated peptide comprising an amino acid sequence SEQ ID NO:6.

On p. 17-18 of the response, Applicant argues that none of the cited reference teach the claimed peptides comprising SEQ ID NO:2 because independent claim 6 has been amended to recite that the claimed peptide are “derived from the ankyrin binding domain of an L1-CAM family member protein” and “promote neurite outgrowth”.

Applicant's arguments have been fully considered but they are not persuasive.

In contrast, for the reasons set forth above in section of the 102 rejection at paragraph 10, the protein of neurofascin (or L1) or the protein with a FIGQY->F motif as taught by Tuvia or Garver meets the limitation of “comprising an amino acid sequence SEQ ID NO:2” and having the activity of “promoting neurite outgrowth” as recited in independent claims 6 and 19. The '140 patent teaches the antennapedia homeodomain pAntp (43-58) (SEQ ID NO:4), which is 100% identical to instant SEQ ID NO:6 as recited in instant claims 7, 22 and 23, to enhance the penetration of the protein into the cell membrane and can be effectively internalized by the cells (see col. 14, line 56-col.15, line2, in particular). Thus, it would have been obvious to a skilled artisan at the time the instant invention was made to fuse the peptide comprising SEQ ID NO:2 to a peptide comprising SEQ ID NO:6 to enhance the membrane penetration of the claimed peptide into the cell.

Conclusion

12. NO CLAIM IS ALLOWED.

13. This application contains claims 1-4 and 8-17 drawn to an invention nonelected with traverse in the reply filed on 6/2/08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

14. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/

Chang-Yu Wang, Ph.D.

May 28, 2009

/Christine J Saoud/

Primary Examiner, Art Unit 1647